


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ZP041151TCP	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/CN2004/001044	International filing date (<i>day/month/year</i>) 14.Sep.2004(14.09.2004)	Priority date (<i>day/month/year</i>) 17.Sep.2003(17.09.2003)
International Patent Classification (IPC) or national classification and IPC IPC7: C12N15/10, 15/62, 15/80, 15/81,15/64,C07K14/37, A61K35/84, A61P37/00,37/06,3/10,31/04,31/12		
Applicant YEASTERN BIOTECH CO.LTD		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 07.Apr.2005(07.04.2005)	Date of completion of this report 18.Jul.2005(18.07.2005)	
Name and mailing address of the IPEA/CN The State Intellectual Property Office, the P.R.China, 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088 Facsimile No. 86-10-62019451	Authorized officer  Telephone No. (86-10)62085300	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/001044

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☐ the description:

pages _____ as originally filed/furnished

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

- ☐ the claims:

pages _____ as originally filed/furnished

pages * _____ as amended (together with any statement) under Article 19

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

- ☐ the drawings:

pages _____ as originally filed/furnished

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/CN2004/001044

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

This questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 29-30

because:

☒ the said international application, or the said claims Nos. 29-30

relate to the following subject matter which does not require an international preliminary examination(*specify*):

Claims Nos. 29-30 relate to methods for treatment of the human or animal body.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☒ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/001044

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement:

Novelty (N)	Claims <u>1-20、 22-23</u>	YES
	Claims <u>21、 24-28</u>	NO
Inventive step (IS)	Claims <u>1-20、 22-23</u>	YES
	Claims _____	NO
Industrial applicability (IA)	Claims <u>1-28</u>	YES
	Claims _____	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: JP2032026A

D2: THE JOURNAL OF BIOLOGICAL CHEMISTRY, VOL.264, NO.1, 1989, Kohsuke kino et al, "Isolation and Characterization of a New Immunomodulatory Proein, Ling Zhi-8(LZ-8), from Ganoderma lucidium", Pages 472-478.

D3: Eur. J. Biochem. VOL. 228, 1995, Ko et al, "A new fungal immunomodulatory protein, FIP-fve isolated from the edible mushroom, Flammulina velutipes and its complete amino acid sequence", Pages 244-249.

D4: US5334704A

D5: Pharmaceutical Biotechnology, vol.9 no. 1, 2002, YE Boping ETAL, "Prokaryotic Expressing of LZ-8 Gene in E-Coli", Pages 21-23.

RE Item V

Reasoned statement under Rule 66.2(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Novelty, Article 33(2) PCT.

D1-D5 disclosed fungal immunomodulatory proteins, which were the same protein as claim 21, no matter where they were isolated from and how they were made. Thus claim 21 is not novel, and does not meet the criteria set out in PCT Article 33(2).

D5 related to a composition comprising a fungal immunomodulatory protein isolated from Ganoderma, its uses of alleviating inflammation, inhibiting viruses, modulating immunological activity. So claims 24-28 are not novel, and do not meet the criteria set out in PCT Article 33(2).

Supplemental Box

Claims 1-20,22-23 appear to be novel and meet the criteria set out in PCT Article 33(2), because the prior art does not disclose the said nucleic acid molecule, the expression vector comprising the molecule, the host cell transfected by the vector, the method of producing host cell transfected by a fungal immunomodulatory protein isolated from Ganoderma, and the purification method.

Inventive step, Article 33(3) PCT.

Claims 1-20,22-23 are considered involve inventive steps, having regard to the prior art, they are not obvious to a person skilled in the art. Therefore, the claims 1-20,22-23 meet the criteria set out in PCT Article 33(3).

Industrial applicability, Article 33(4)PCT.

Claims 1-28 meet the criteria set out in PCT Article 33(2)-(3), for industrial applicability.

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ on paper
- ☒ in electronic form
- c. time of filing/furnishing
- ☐ contained in the international application as filed
- ☒ filed together with the international application in electronic form
- ☐ furnished subsequently to this Authority for the purposes of search and/or examination
- ☐ received by this Authority as an amendment * on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

**If item 4 in Box No.I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*

第VIII(ii)栏 声明：有权申请和被授予专利

声明必须与规程 212 条的标准语句一致：参见对于 VIII、VIII(i)到(v) (概述) 的说明和专门对于 VIII(ii) 的说明。如果不使用本栏，则请求书中不应包括此页。

当根据细则 4.17(iv)的声明不适用时，在国际申请日时，申请人有权申请和被授予专利的声明(细则 4.17(ii)和 51 之二.1(a)(ii)):

关于本国际申请

益生生技开发股份有限公司基于下列事项有权申请和被授予专利：

益生生技开发股份有限公司作为发明人柯俊良、黄玉儒、陈子智、洪旭伟、江乐隆、胡庆龙、官振群、周宣如的雇主是有权的；

本声明是对除美国以外的所有指定国。

关于本国际申请

宝纳纯生技公司基于下列事项有权申请和被授予专利：

益生生技开发股份有限公司于 2004 年 9 月 1 日对宝纳纯生技公司的允诺；

本声明是对除美国以外的所有指定国。

☐ 本声明下转声明续页中“续第 VIII (ii) 栏”。

第VIII(iv)栏 声明：发明人资格声明（仅为了指定美国的目的）

声明必须与规程 214 条的标准语句一致；参见对于 VIII、VIII(i)到(v) (概述)的说明和专门对于 VIII(iv)的说明。如果不使用本栏，则请求书中不应包括此页。

发明人资格声明 (细则 4.17(iv)和 51 之二.1(a)(iv))
为了指定美国的目的：

我在此声明我相信我是要求保护和寻求专利的主题的原始、最初和唯一的（如果只列出了一个发明人）或者共同的（如果列出了不只一个发明人）发明人。

本声明是本国际申请的一个组成部分（如果本声明与国际申请一起提出）。

本声明是关于 PCT/_____号国际申请的（如果本声明根据细则 26 之三提出）。

我在此声明我的居所，邮寄地址和国籍和列在我名字下面的一样。

我在此声明我已检查过并理解上述国际申请的内容，包括所述申请的权利要求书。在所述申请的请求书中，我按照 PCT 细则 4.10 写明了对外国优先权的任何要求，并且在下面的“在先申请”栏目下，通过申请号，国家或世界贸易组织成员，申请的日、月、年，我写明了向美国以外的国家提出的，其申请日早于所要求的外国优先权申请的申请日的任何专利申请或者发明人证书申请，包括指定至少一个除美国以外的国家的任何 PCT 国际申请。

在先申请：_____ 60/503,547, US

_____ 17.09 月 2003 (17.09.2003)

我在此承认自己有义务公开我知道的，根据美国联邦法规（CFR）第 37 篇第 1.56 条对确定专利性有实质意义的信息，包括对于部分继续申请，在该在先申请的申请日和该部分继续申请的 PCT 国际申请日之间可得到的实质性信息。

我在此声明所有根据我自己的知识所作的声明是真实的，并且所有根据信息和相信所作的声明相信是真实的；而且在作这些声明时我知道根据美国法典第 18 篇第 1001 条故意作假声明以及有关类似行为将受到罚款或监禁或二者并罚的惩罚，并且这样的故意假声明将危害申请或根据该申请授予的任何专利的有效性。

姓名：_____ 柯俊良

居所(城市 and 美国的州(适用时)，或国家)：_____ 台北，中国

邮寄地址：_____ 中国台湾台北县汐止市康宁街 169 巷 23-3 号 6 楼 221

国籍：_____ CN

发明人的签字：_____ 柯俊良 日期：_____ 2004/9/16

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（未包括在请求书中的签字日期，或是根据细则 26 之三在提出国际申请之后更正或增加的声明之日期）

姓名：_____ 黄玉儒

居所(城市 and 美国的州(适用时)，或国家)：_____ 台北，中国

邮寄地址：_____ 中国台湾台北县汐止市康宁街 169 巷 23-3 号 6 楼 221

国籍：_____ CN

发明人的签字：_____ 黄玉儒 日期：_____ 2004/9/16

（如果签字未包括在请求书中，或如果声明是根据细则 26 之三在提出国际申请之后更正或增加的。该签字必须是发明人的签字，而不是代理人的签字）

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续第VIII(i)至(v)栏 声明

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姓名: 陈子智

居所(城市 and 美国的州(适用时), 或国家): 台北, 中国

邮寄地址: 中国台湾台北县汐止市康宁街 169 巷 23-3 号 6 楼 221

国籍: CN

发明人的签字: 陈子智 日期: 2004.9.2

(如果签字未包括在请求书中, 或如果声明是根据细则 26 之三在提出国际申请之后更正或增加的。该签字必须是发明人的签字, 而不是代理人的签字) (未包括在请求书中的签字日期, 或是根据细则 26 之三在提出国际申请之后更正或增加的声明之日期)

姓名: 洪旭伟

居所(城市 and 美国的州(适用时), 或国家): 台北, 中国

邮寄地址: 中国台湾台北县汐止市康宁街 169 巷 23-3 号 6 楼 221

国籍: CN

发明人的签字: 洪旭伟 日期: 2004.9.2

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姓名: 江乐隆

居所(城市 and 美国的州(适用时), 或国家): 台北, 中国

邮寄地址: 中国台湾台北县汐止市康宁街 169 巷 23-3 号 6 楼 221

国籍: CN

发明人的签字: 江乐隆 日期: 2004.9.2

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姓名: 胡庆龙

居所(城市 and 美国的州(适用时), 或国家): 台北, 中国

邮寄地址: 中国台湾台北县汐止市康宁街 169 巷 23-3 号 6 楼 221

国籍: CN

发明人的签字: 胡庆龙 日期: 9/6/2004

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姓名: 官振群

居所(城市 and 美国的州(适用时), 或国家): 台北, 中国

邮寄地址: 中国台湾台北县汐止市康宁街 169 巷 23-3 号 6 楼 221

国籍: CN

发明人的签字: 官振群 日期: 9/8/2004

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姓名: 周宣如

居所(城市 and 美国的州(适用时), 或国家): 台北, 中国

邮寄地址: 中国台湾台北县汐止市康宁街 169 巷 23-3 号 6 楼 221

国籍: CN

发明人的签字: 周宣如 日期: 9/6/2004

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